REMARKS

Claim Status:

Claims 1-2, 4-9, and 11-22 are pending and elected claims 3 and 10 should be examined with new claims 16-22, which are supported in the specification as-filed.

Priority:

The claim for priority is updated and now indicates that U.S. Application No. 09/514,245, filed February 28, 2000, issued as U.S. Patent No. 6,703,023. See Office Action of April 27, 2005, pages 2-3.

Rejections under 35 U.S.C. § 112 (enablement):

Claims 3 and 10 are rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. Office Action, pages 3-4. These claims have been canceled without prejudice or disclaimer. Thus, the rejection should be withdrawn.

New claims 16-22 are believed to avoid this issue and are therefore allowable. Specifically, the PTO alleges "the specification, while being enabling for method of utilizing ORF2 of Porcine Circovirus type 2 or type B only, does not reasonably provide enablement for method detecting antibodies against any and all circovirus in general, or porcine circovirus in particular." *Id.* That is, the PTO alleges "the field of viral detection is considered to be highly unpredictable. [A]bsent teaching which polypeptide would be efficacious for detection, the skilled artisan would be forced to conduct large quantity of experimentations to enable the full scope of the claimed invention." *Id.* Applicants respectfully traverse the grounds for this rejection.

Under 35 U.S.C § 112, to be "enabling," the specification must teach the skilled artisan how to make and use the invention. A determination of what level of experimentation is

"undue," so as to render a disclosure non-enabling, is made from the viewpoint of persons experienced in the field of the invention. *Elan Pharm., Inc. v. Mayo Found. For Med. Educ. and Research*, 346 F.3d 1051 (Fed. Cir. 2003). "The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Undue experimentation requires consideration of several factors, including, but not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

Applying the *Wands* factors to the instant invention, as enumerated below, the skilled artisan would understand the application to provide an enabling disclosure for detecting and quantifying antibodies directed against circoviruses.

The present specification enables the breadth of the claims. That is, the specification provides enabling support for detecting and quantifying antibodies against circoviruses. For example, the specification makes clear "the present invention likewise relates to specific polypeptides of known porcine circoviruses other than PWD circovirus...." Specification, page 25, lines 5-9. In fact, the specification discloses "labeled or unlabeled mono- or polyclonal antibodies directed against said specific polypeptides encoded by said consensus nucleotide sequences are also part of the invention." *Id.* at lines 10-12. Furthermore, the invention contemplates "corresponding polypeptides as well as said antibodies directed against said polypeptides in procedures or sets for detection and/or identification ... specific PWD circovirus type ... B." *Id.* at lines 13-17. That is, the invention embodies polypeptide sequences from several porcine circoviruses, antibodies directed against these polypeptide sequences, and methods for detecting these antibodies.

The specification discloses also "the polypeptides according to the invention, the antibodies according to the invention described below, and the nucleotide sequences according to the invention can advantageously be employed in procedures for the detection and/or identification of PWD circovirus, or of porcine circovirus other than a PWD circovirus." Specification, page 33, lines 22-25. That is, the specification discloses that the inventive nucleotide sequences and antibodies can be used to detect a PWD circovirus or a porcine circovirus other than a PWD circovirus. Moreover, the specification provides several methods for detecting any porcine circovirus in a biological sample. For example, at page 34, lines 3-13, the specification discloses a method for detecting a porcine circovirus in a biological sample by contacting the biological sample with an inventive polypeptide and demonstrating antigen-antibody complex formed. The specification makes clear "any conventional procedure can be employed for carrying out such a detection of the antigen-antibody complexes...." Specification, page 34, lines 21-22. For example, ELISA may be performed, as described at page 34, lines 1-14. Thus, the specification provides an enabling disclosure for detecting and quantifying antibodies directed against several porcine circoviruses, including Type B circoviruses.

Because Applicants' disclosure enables the skilled artisan to detect and quantify antibodies directed against circoviruses, the disclosure enables the full breadth of the claims.

The nature of the invention and the state of the prior art enable the skilled artisan to detect and quantify antibodies against several porcine circoviruses. Using conventional molecular and immunological techniques, as known in the art and described in the specification (*e.g.* page 34, lines 1-14), Applicants have successfully developed a method for detecting and quantifying antibodies against several porcine circoviruses. Because the present invention, in conjunction with the state of the art, provides materials and methods for detecting antibodies specific to porcine circoviruses, the nature of the invention and state of the prior art enables the skilled artisan to predictably and reproducibly detect porcine circovirus-specific antibodies.

Applicants' disclosure provides sufficient direction and several examples that enable the predictable and reproducible detection of antibodies directed against a porcine circovirus. As disclosed in Example 6, the specification provides direct guidance for detecting and quantifying porcine circovirus antibodies using, for example, ELISA. Thus, the present invention enables the skilled artisan to predictably and reproducibly detect and quantify antibodies directed against porcine circoviruses.

Finally, it is worth emphasizing that Applicants have characterized and expressed SEQ ID NOS: 23, 25, and 27, i.e., ORF'1-'3. It is believed that no other reference of record describes an analogous characterization or expression.

Because the as-filed specification provides sufficient direction and guidance for detecting antibodies directed against a porcine circovirus of Type B, the new claims are supported by an enabling disclosure. Accordingly, the rejection should not apply to the new claims and should be withdrawn.

Rejections under 35 U.S.C. § 112, first paragraph (written description):

Claims 3 and 10 are rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of written description. Office Action, pages 4-6. These claims have been canceled without prejudice or disclaimer. Thus, the rejection should be withdrawn.

New claims 16-22 are believed to avoid this issue and are therefore allowable. Specifically, the PTO alleges "[A]pplicants have only disclosed the sequence identified as ORF2 of Porcine Circovirus type 2 or type B. There is no information in the specification that indicates that Applicants were in possession of the claimed "circoviruses" in general or "porcine circoviruses" in particular that can be utilized in the claimed invention." *Id.* at page 4. That is, the PTO takes the position "a written description of all other claimed circoviruses beside the ORF2 of circovirus should be disclosed to overcome this rejection." *Id.* at page 6. Applicants respectfully traverse the grounds for this rejection.

As explained in response to the Section 112 enablement rejections, Applicants have characterized and expressed SEQ ID NOS 23, 25, and 27, i.e., ORF'1-'3. It is believed that no other reference of record describes an analogous characterization or expression.

Moreover, the as-filed specification provides written support for detecting and quantifying antibodies directed against circoviruses. That is, the invention contemplates "corresponding polypeptides as well as said antibodies directed against said polypeptides in procedures or sets for detection and/or identification ... specific PWD circovirus type ... B." Specification, page 25, lines 13-17. That is, the invention embodies polypeptide sequences from several porcine circoviruses, antibodies directed against these polypeptide sequences, and methods for detecting these antibodies.

The specification discloses that the inventive nucleotide sequences and antibodies can be used to detect a PWD circovirus or a porcine circovirus other than a PWD circovirus. For example, "the polypeptides according to the invention, the antibodies according to the invention described below, and the nucleotide sequences according to the invention can advantageously be employed in procedures for the detection and/or identification of PWD circovirus, or of porcine circovirus other than a PWD circovirus." Specification, page 33, lines 22-25. Additionally, the specification provides several methods for detecting any porcine circovirus in a biological sample. For example, at page 34, lines 3-13, the specification discloses a method for detecting a porcine circovirus in a biological sample by contacting the biological sample with an inventive polypeptide and demonstrating antigen-antibody complex formed. The specification makes clear "any conventional procedure can be employed for carrying out such a detection of the antigen-antibody complexes...." Specification, page 34, lines 21-22. For example, ELISA may be performed, as described at page 34, lines 1-14. Thus, the specification discloses detecting and quantifying antibodies directed against several porcine circoviruses, including Type B circoviruses.

Because the as-filed application discloses a method for detecting and quantifying antibodies directed against circoviruses, the disclosure supports claims 3 and 10. Accordingly, the rejection is improper and should be withdrawn.

Rejections under 35 U.S.C. § 102:

There are three anticipation rejections. Applicants respectfully traverse each of the grounds for this rejection under one section.

Claims 3 and 10 are rejected under 35 U.S.C. § 102 (b) as allegedly anticipated by Tischer et al. (Arch. Virology, 1995, Vol. 140: 737-743). The PTO alleges "Tischer et a. taught development of enzyme linked immunosorbent assay (ELISA) for detecting the porcine circovirus antibodies (see the abstract)." Office Action, page 6.

Claims 3 and 10 are rejected under 35 U.S.C. § 102 (b) as allegedly anticipated by Allen et al. (Veterinary Immunology and Immunopathology, 1994, Vol. 43: 357-371.). Specifically, the PTO alleges "Allen et al. taught development of enzyme linked immunsorbent assay (ELISA) for detecting the porcine circovirus in pigs (see the abstract)." Office Action, page 7.

Claim 3 is rejected under 35 U.S.C. § 102 (b) as allegedly anticipated by Dulac et al (Cancer J. Vet. Res. 1989, Vol. 53, pages 431-433). The PTO alleges "Dulac et al. set forth development of enzyme linked immunosorbent assay (ELISA) for detecting the porcine circovirus in pigs (see the abstract, page 431, last paragraph, page 432.)" Office Action, page 7.

The rejected claims have been canceled without prejudice or disclaimer. Thus, the rejection should be withdrawn.

New claims 16-22 are believed to avoid this issue and are therefore allowable. The present claims were amended to recite "PCVB." The cited references do not describe anything with respect to PCVB. Since the references do not anticipate subject matter not described, they cannot anticipate the new claims.

Atty. Dkt. No. 042049-0107
Appl. No. 10/718,266

Conclusion

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

Date 10-27-2005

By _____ (45,943)
SEANA. PASSINO FOR
Stephen B. Maebius
Attorney for Applicants
Registration No. 35,264

FOLEY & LARDNER LLP
Customer Number: 22428
22428
PATENT TRADEMARK OFFICE
Telephone: (202) 672-5571
Facsimile: (202) 672-5399

Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 19-0741 for any such fees; and applicant(s) hereby petition for any needed extension of time.